

REMARKS

In response to the April 10, 2006 Restriction Requirement, Claims 1-23 and 33 were cancelled. In a May 2, 2006 Preliminary Amendment, new Claims 34-50 were added. Claims 37, 39 and 40 were withdrawn in response to the June 23, 2006 Election of Species. New Claim 51 is presently added. Accordingly, Claims 24-32, 34-36, 38 and 41-51 are currently pending.

Present Invention

The present invention is a method of inhibiting the intrusion of micro-organisms into a body cavity of a mammal by applying a hydrogel composition. The hydrogel comprises a poly(N-vinyl lactam), a polysaccharide, and water. The hydrogel has novel characteristics. For example, the hydrogel exhibits sanitizing and disinfecting activity without the inclusion of antimicrobial/antibiotics. (See page 5, lines 26-27, of the specification.)

The polyvinyl lactam and the polysaccharide are present in the hydrogel in a specific ratio. (See page 5, lines 13-14, of the specification.) Independent Claim 24 has been amended to recite that the range of the ratio of the amount by weight of the poly(N-vinyl) lactam to the amount by weight of the polysaccharide is about 1 : 5 to about 75 : 1. Support for this amendment is on page 7, lines 2-4 and 6-8.

Independent Claim 24 has also been amended to recite that the water content of the hydrogel is about 25 wt% to 90 wt%. Support for this amendment is on page 8, lines 23-26.

Rejection under 35 U.S.C. §103

Claims 24-32, 34-36, 38 and 41-50 are rejected under 35 U.S.C. §103 as being unpatentably obvious over Beckman *et al.* (U.S. Patent Application No. 2002/0015697, hereinafter "*Beckman*"). (See Office Action pages 4-6.)

Beckman provides a method for reducing a microbial population on a surface with a composition that comprises a transition metal as the active ingredient. In particular, *Beckman* state that their compositions reduce microbial populations by causing a "transition metal overload." (See paragraph [0040] of *Beckman*). That is, *Beckman* requires a transition metal for reducing microbial populations. Along with the transition metal, the *Beckman* composition includes a non-oxidant stress inducer such as chitosan.

The composition of the instant invention is a hydrogel. The hydrogel is a lubricious gelatinous composition. (See page, 5, lines 13-14, and page 6, lines 19-20, of the specification.) Independent Claim 24 has been amended to emphasize that the composition is in the form of a hydrogel. Support for this amendment is throughout the specification including page 6, lines 20-21.

The hydrogel contains a poly(N-vinyl lactam), a polysaccharide, and water. The poly(N-vinyl lactam) and the polysaccharide are present in specific relative amounts. The water content of the hydrogel is at least 25 wt%.

Independent Claim 24 has been amended to recite that the range of the ratio of the amount by weight of the poly(N-vinyl) lactam to the amount by weight of the polysaccharide is about 1 : 5 to about 75 : 1. Support for this amendment is on page 7, lines 2-4 and 6-8.

Independent Claim 24 has also been amended to recite that the water content of the hydrogel is about 25 wt% to 90 wt%. Support for this amendment is on page 8, lines 23-26.

In contrast to the pending claims, *Beckman* does **not** disclose a hydrogel (i.e., does **not** disclose a lubricious gelatinous composition). The only place in their patent where *Beckman* mentions including water in their composition is in paragraph [0155]. Water is added to form an **oral rinse**. Clearly, an oral rinse is **not** in the form of a hydrogel.

In paragraph [0145], *Beckman* provides a long laundry list of additional materials that could be added to their composition. Included in that long list is polyvinylpyrrolidone. However, *Beckman* does **not** specify any particular ratio of the non-oxidant stress inducer to the polyvinylpyrrolidone.

Moreover, unlike the *Beckman* composition, the hydrogel of the instant invention provides disinfecting/sanitizing activity without transition metals and without antibiotics.

In order for a *prima facie* case of obviousness to be made, the prior art reference must teach or suggest all the claim limitations. (See MPEP §2142.) *Beckman* do **not** disclose all the claim limitations of the pending claims. In particular, *Beckman* do **not** disclose all the claim limitations of pending independent Claim 24. To summarize:

- *Beckman* do **not** disclose hydrogels.
- *Beckman* do **not** include water in their composition to form a hydrogel.
- *Beckman* do **not** include water in at least 25 wt% in their composition to form a hydrogel.
- *Beckman* do **not** disclose a relative amount of a poly(N-vinyl) lactam to a polysaccharide.

Since *Beckman* does **not** disclose all the claim limitations of the pending claims, the pending claims can **not** be obvious in view of *Beckman*.

New Claim 51

New Claim 51 recites that the composition of Claim 24 further comprises a spermicide. This claim recites a subset of the therapeutic agents recited in Claim 32. No new matter was added.

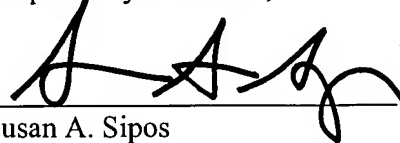
Obvious Type Double Patenting Rejection under 35 U.S.C. §101

The Examiner has also provisionally rejected Claims 24-32, 34-36, 38 and 41-50 under the judicially created doctrine of obvious type double patenting as being unpatentable over all the claims of the co-pending divisional application (U.S. Serial No. 11/416,060). (See Office Action pages 2 and 3.)

Once the instant application is allowed, Applicants will file a terminal disclaimer which would ensure that the patent term of the patent that issues from this application would not extend beyond the term of any patent issued from Application Serial No. 11/416,060.

Applicants respectfully submit that the application is in all respects complete and in condition for examination and favorable consideration, which action is earnestly solicited. If the Examiner has any questions or comments, it is respectfully requested that the Examiner contact Applicants' undersigned attorney at the telephone number provided below.

Respectfully submitted,



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